

Louisiana Office of Public Health Laboratories	
Test Name	IgM Antibody to Hepatitis B Core Antigen EIA
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	86705
Synonyms	Anti-HBc IgM
Brief Description of Test	The MONOLISA™ Anti-HBc IgM EIA is an enzyme immunoassay intended for use in the qualitative detection of IgM antibodies to hepatitis B core antigen (anti-HBc IgM) in human serum. Assay results may be used with other HBV serologic markers for the laboratory diagnosis of HBV disease associated with HBV infection.
Possible Results	Nonreactive Borderline Reactive
Reference Range	Nonreactive
Specimen Type	Serum
Specimen Container(s):	Red top tubes, Marble top tubes, polypropylene vials
Minimum volume accepted:	210 µL serum
Collection Instructions	<p>Specimens should only be collected by personnel that have been properly trained. Care should be taken during specimen collection and handling to avoid generation of aerosols. Blood should be collected in a plastic tube, such as a vacutainer, which does not contain an anticoagulant. The collection tube may or may not contain a serum separator. If collected in a tube without serum separator, serum must be aliquoted into screw cap tubes before shipment to laboratory. Depending on the type of collection tube, the amount of time it will take for the blood to clot could take up to 60 minutes. Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to NCCLS guidelines.</p> <p>Follow the package insert for the collection tube you use.</p> <p>Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique.</p>

	<p>Complete a Lab Form 96 to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date of collection, time of collection, test requested, and submitter's name, address, and contact number.</p> <p>Two unique identifiers MUST be recorded on the tube AND the Lab 96 form. A missing identifier on the tube will be an automatic rejection. If the identifiers are missing from the Lab 96 form, the submitter must be contacted and a new form with this information must be faxed back to the lab before testing will take place.</p> <p>Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.</p>
Storage and Transport Instructions	<p>Specimens must be shipped refrigerated (2-8°C) and can be stored for up to 7 days.</p> <p>For longer storage, serum should be poured into a sterile screw cap tube and be frozen at -20°C or colder. Frozen specimens must be shipped on dry ice and received at a temperature of -20°C or colder. If samples are frozen, document the date and time the sample was frozen.</p>
Causes for Rejection	<p>Unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), incorrect specimen type, or expired collection tubes must be rejected. Improper storage and improper transport temperature requirements are also reasons for rejection.</p>
Limitations of the Procedure	<p>A nonreactive test result does not exclude the possibility of exposure to hepatitis B virus.</p> <p>Results from immunosuppressed patients should be interpreted with caution.</p> <p>A reactive anti-HBc IgM result does not exclude co-infection by another hepatitis virus.</p> <p>The performance of the BioRad MONOLISA™ Anti-HBc EIA has not been established with cord blood, neonatal specimens, cadaver specimens, or body fluids other than serum or plasma, such as saliva, urine, amniotic, or pleural fluids.</p>
Interfering Substances	<p>No clinically significant effect has been detected in assay results with increased levels of protein, lipids, bilirubin, or hemoglobin.</p>
References	<p>BioRad MONOLISA™ Anti-HBc IgM EIA Package Insert. EVOLIS™ Operator Manual</p>
Additional Information	<p>None</p>
Release Date	<p>03/15/2016</p>

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